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August 15, 2018

Via CM/ECF and Email

The Honorable Joan N. Ericksen
12W U.S. Courthouse
300 South Fourth Street
Minneapolis, MN 55415

Re: *In re Bair Hugger Forced-Air Warming*, MDL No. 15-2666-JNE-DTS

Dear Judge Ericksen:

Nine months after this Court denied their general causation motions, Defendants seek another bite at the apple. (Doc. 1428) Defendants base their request for leave to file a motion for reconsideration not on groundbreaking new evidence, but on a rehash of prior attacks. Absent any valid factual or legal reason to grant their request for a do-over under Local Rule 7.1(j), Defendants alternatively seek leave to move for reconsideration so that they may appeal this Court's otherwise non-appealable general causation rulings pursuant to 28 U.S.C. § 1292(b). For any of the following reasons, the Court should deny Defendants' belated effort to re-plow old ground.

Permission for leave to file a motion for reconsideration may be granted only under "compelling circumstances." D. Minn. L.R. 7.1(j). Compelling circumstances include the correction of "manifest errors of law or fact." *Dixon v. Fresh Seasons Mkt., LLC*, 2015 WL 6872461, at *1 (D. Minn. 2015). This Court routinely denies leave to file such motions where, as here, the movant "has not shown any compelling circumstances warranting reconsideration." *Edeb v. Equifax Info, LLC*, 2013 WL 1173920, at *1 (D. Minn. 2013). In fact, this Court summarily rejected Plaintiffs' request for leave to file a motion to reconsider its March 6, 2017 Order denying Plaintiffs' timely motion to overrule Defendants' objection to VitaHEAT evidence, despite its relevance. (Doc. 282.)

Defendants' request here fares no better. At the outset, Defendants contend that "Plaintiffs' medical experts' opinions rest on a three-legged stool" comprised solely of Dr. Elghobashi's CFD, internal contamination studies, and the McGovern study. This is a false premise. Besides this evidence, Plaintiffs' experts relied on *hundreds* of other sources. Dr. Samet, for instance, reviewed 196 independent sources of evidence—ranging from peer-reviewed literature such as the Darouiche study, to 3M documents acknowledging that Bair Hugger increases PJI, to deposition testimony of numerous witnesses—in concluding that the device can cause PJI. *See In re PPA*, 289 F. Supp. 2d 1230, 1243 (W.D. Wash. 2003) (multiple lines of evidence showed reliability of expert's general causation testimony). None of this evidence has been refuted or withdrawn from publication. The very premise of Defendants' argument thus fails to warrant an "extraordinary" request to file a

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motion for reconsideration, much less reversal of this Court's general causation rulings. *See Edeb*, 2013 WL 1173920, at *1.

First, Defendants argue that Dr. Elghobashi's CFD alone does not "establish general causation." This is a red herring. With or without that CFD, a volume of peer-reviewed studies shows that the Bair Hugger disrupts airflow, including Legg 2012, Legg 2013, Belani 2013, and Defendants' own study (Sessler 2011). Tellingly, Defendants make no mention of these additional airflow studies, hoping to convince the Court that Dr. Elghobashi's CFD is the only such study when it is not. *See, e.g., Milward v. Acuity*, 639 F.3d 11, 25 (1st Cir. 2011) ("Dr. Smith did not infer causality from this suggestion alone, but rather from the accumulation of multiple scientifically acceptable inferences from different bodies of evidence."). Defendants also speculate that the boundary conditions in Dr. Elghobashi's CFD do not match any operating room in any case in this MDL, but they ignore that Dr. Elghobashi has opined that the Bair Hugger would disrupt airflow in any operating room. *See* TT 975:5-976:21. And Defendants forget that they rely on Dr. Memarzadeh's CFD and Dr. Sessler's particle studies to support their public safety claim of "Bair Hugger for Everyone" despite the unique conditions used in each of those experiments.

Second, Defendants assert that the Court "has now ruled that the 'dirty machines' theory is inadmissible." It has not. Defendants admit, as they must, that the Court precluded evidence in *Gareis* that the Bair Hugger harbors dangerous bacteria, but the Court has not extended that ruling to "every case." Nor do Defendants cite a single case where a court has transformed an evidentiary ruling in one bellwether case into a dispositive ruling in thousands of other cases. Either way, the evidence relied upon by Plaintiffs' medical experts goes far beyond that theory of the case.

Third, despite their criticism of observational studies and post-distribution evidence, Defendants claim that "Dr. Reed's new study demonstrates that the McGovern study is unreliable." Nonsense. While Dr. Reed's study reports that MSSA screening reduced PJI rates by around 25%, McGovern reports a far greater reduction in PJI rates from use of air-free warming. Implementation of MSSA screening thus cannot account for the reduction in PJI rates reported in McGovern. Dr. Reed and colleagues admit as much, noting that "improvement in infection rates could have been [due] to *other factors*" than MSSA screening. They also agree that MSSA screening remains a "contentious issue and the most recent international consensus statement of PJI chose to not recommend universal decolonization of all patients." At best, then, the results of Dr. Reed's study might go to weight, not admissibility. *See Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1995). Finally, Dr. Reed testified that despite changes in some protocols such as MSSA screening, he stands behind McGovern's conclusions.

In sum, Defendants have not presented compelling circumstances warranting reconsideration of the Court's general causation rulings. Their desire to file an interlocutory appeal does not change that fact. Indeed, Defendants' misinterpretation of *Glastetter*—a per curiam decision excluding expert testimony unsupported by epidemiologic evidence—is no more persuasive now than when this Court declined to impose a "scientifically convincing" standard for medical expert testimony that runs counter to established principles of *Daubert* and Eighth Circuit law. (*See* Doc. 879 at 12–14.)

Respectfully submitted,

Genevieve Zimmerman, for Plaintiffs